

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

PAMELA BUTLER, et al.,	)	
	)	
<i>Plaintiffs,</i>	)	Case No. 4:18-cv-01701-AGF
v.	)	
	)	
MALLINCKRODT LLC, et al.,	)	Lead Case
	)	
<i>Defendants.</i>	)	

**MALLINCKRODT’S STATEMENT OF UNCONTROVERTED MATERIAL FACTS  
IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

Defendant Mallinckrodt LLC (“Mallinckrodt”) submits the following uncontroverted material facts in support of its Motion for Summary Judgment. Sections I, II and III of Mallinckrodt’s Statement of Facts is identical to Cotter Corporation (N.S.L.)’s (“Cotter”) Statement of Facts. Section IV, for both Cotter and Mallinckrodt, is particular to each defendant.

**I. INSTITUTE OF SUIT AND CASE MANAGEMENT ORDERS.**

1. Plaintiffs filed suit against Defendants Mallinckrodt and Cotter on October 5, 2018, asserted a single public liability cause of action pursuant to the Price-Anderson Act, and sought damages for personal injuries. (ECF No. 1.)

2. Plaintiff Pamela Butler alleged radiation caused her breast cancer. (ECF No. 1, Butler Compl. at ¶ 24; *see also* ECF No. 52-4, Defs.’ Ex. A4, Hu Report as to Butler.)

3. Butler alleged she lived in the vicinity of Coldwater Creek from 1983 to 1993. (*Id.*)

4. Plaintiff Kenneth Koterba alleged radiation caused his brainstem tumor. (*See* Case No. 4:18-cv-01702-AGC, ECF No. 1, Koterba Compl. at ¶ 24; *see also* ECF No. 52-3, Defs.’ Ex. A3, Hu Report as to Koterba.)

5. Koterba alleged he lived in the vicinity of Coldwater Creek since 1964. (*Id.*)

6. Plaintiff Anthony Hines alleged radiation caused his mantle cell lymphoma. (*See* Case No. 4:18-cv-01703-AGF, ECF No. 1, Hines Compl. at ¶ 24; *see also* ECF No. 52-1, Defs.’ Ex. A1, Hu Report as to Hines.)

7. Hines alleged he lived in the vicinity of Coldwater Creek from 1962 to 1974 and from 1976 to 1982. (*Id.*)

8. Plaintiff Emery Walick alleged radiation caused his medulloblastoma. (*See* Case No. 4:18-cv-01704-AGF, ECF No. 1, Walick Compl. at ¶ 24.)

9. Walick alleged he lived in the vicinity of Coldwater Creek from 1990 to 1997, 2008 to 2010, and 2012 to 2014. (*Id.*)

10. On October 15, 2018, Chief Judge Rodney Sippel entered an “Administrative Order Regarding Radionuclide Exposure Claims against Mallinckrodt LLC and/or Cotter Corporation (N.S.L.).” (ECF No. 63-10.) (The Court vacated this order with respect to other cases on April 12, 2022. ECF No. 111.)

11. On the same day, this Court entered Case Management Order No. 14 for Future Consolidated Cases Filed Against Cotter Corporation (N.S.L.) and/or Mallinckrodt, LLC. (ECF No. 63-9.)

12. The four lawsuits asserted by these plaintiffs were consolidated into *McClurg* on November 13, 2018. (*Scott D. McClurg v. Mallinckrodt, Inc., et al.*, 4:12-cv-00361-AGF, ECF No. 751.)

13. On June 16, 2019, the Court entered Case Management Order No. 1 for these consolidated cases, which included additional deadlines to govern this matter, including a supplemental expert designation deadline. (ECF No. 779.)

14. On November 12, 2020, the Court severed these four plaintiffs from *McClurg* into their current consolidated action under lead Case No. 4:18-cv-01701-AGF, *Pamela Butler, et al. v Mallinckrodt, Inc.*, in the United States District Court for the Eastern District of Missouri. (ECF No. 32.)

15. On August 18, 2021, Defendants filed Joint Motions to Exclude Plaintiffs' Experts. (ECF Nos. 47, 49 and 51.) The Court heard argument on those motions on March 10, 2022. (ECF No. 90.)

16. On March 31, 2022, the Court issued an order partially granting Defendants' motions to exclude plaintiffs' experts. (ECF No. 104, *Mem. and Ord.*)

## **II. THE COURT PARTIALLY GRANTED DEFENDANTS' MOTIONS TO EXCLUDE PLAINTIFFS' EXPERTS.**

17. The Plaintiffs' expert James Clark opined that he could calculate the dose of radiation each Plaintiff received from his or her exposure to the radioactive material. (*Mem. and Ord.* at 16-17; ECF No. 50-11, Defs.' Mot. to Exc. Clark, Exs. K (ECF No. 50-11, Clark Report as to Butler at 1-2), L (ECF No. 50-12, Clark Report as to Hines at 1-2), M (ECF No. 50-13, Clark Report as to Koterba at 1-2), and N (ECF No. 50-14, Clark Report as to Walick at 1-2).)

18. Dr. Clark also opined that the doses he calculated for each Plaintiff were far in excess of "background" levels of radiation. (*Mem. and Ord.* at 18; Clark Report as to Butler at 36; Clark Report as to Hines at 38; Clark Report as to Koterba at 35; Clark Report as to Walick at 25.)

19. Dr. Clark claimed he based his opinion on a methodology contained in the public health assessment done by the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry ("ATSDR"), which he attempted to apply to Plaintiffs without support. (*Mem. and Ord.* at 16-17, 34-35; Clark Report as to Butler at 1-2; Clark Report as to Hines

at 1-2; Clark Report as to Koterba at 1-2; Clark Report as to Walick at 1-2; ECF No. 50-2, Clark Dep. 131:21-24, 255:17-256:7.)

20. Dr. Clark also created his own “background” levels of radiation instead of using the scientifically and legally accepted natural background number of 360 millirem, which is what his principal source utilized. (*Mem. and Ord.* at 20-21; Clark Dep. 123:16-125:8, 131:21-24, 151:25-153:21, 175:19-24, 216:6-11, 217:22-218:14, 255:17-256:7.)

21. The Court excluded Dr. Clark’s opinions in their entirety. (*Mem. and Ord.* at 36-37.)

22. The Plaintiffs expert Howard Hu, M.D., offered a specific causation opinion that radiation caused or contributed to the Plaintiffs’ cancers/tumor based on the doses Dr. Clark calculated and their comparison to Dr. Clark’s background numbers. (*Mem. and Ord.* at 21; ECF No. 52-1, Hu Report as to Hines; ECF No. 52-2, Hu Report as to Walick; ECF No. 52-3, Hu Report as to Koterba; ECF No. 52-4, Hu Report as to Butler.)

23. The Court excluded Dr. Hu’s specific causation opinions that radiation caused or contributed to the Plaintiffs’ cancers/tumor. (*Mem. and Ord.* at 38-39.)

24. The Plaintiffs’ expert James Wells offered an opinion that Mallinckrodt violated applicable federal regulations at SLAPS because it violated 10 C.F.R. § 20.106(b) (1960), 25 Fed. Reg. 8595, 8599 (Sept. 7, 1960). (*Mem. and Ord.* at 6; *see also*, ECF No. 48-1, Defs.’ Mot. to Exc. Wells, Exhibit A, Wells Rep. at 12-16.)

25. Section 20.106 prohibits a licensee from “possess[ing], us[ing] or transfer[ring] licensed material in such a manner as to release into air or water in any restricted area any concentration of radioactive material in excess of limits specified in Appendix B, Table II, of this part.” 10 C.F.R. § 20.106(b) (1960), 25 Fed. Reg. 8595, 8599 (Sept. 7, 1960).

26. The regulation further states that “determinations as to the concentration of radioactive material shall be made with respect to the point where such material leaves the restricted area.” *Id.* § 20.106(c).

27. Dr. Wells did not evaluate the Manhattan Engineering District (“MED”) or Atomic Energy Commission’s (“AEC”) oversight of Mallinckrodt during the applicable time-periods. (ECF No. 48-4, Defs.’ Mot. to Exc. Wells, Exhibit D, Wells Dep. at 148.)

28. Dr. Wells’s opinion that releases of radon-222 at SLAPS were in excess of the federal limits set forth in 10 C.F.R. § 20.106 (1960) was not based on annual averages and was predicated on erroneous factual assumptions controverted by an undisputed factual record. (*Mem. and Ord.* at 6-15 and 26-31; *see also*, ECF No. 48-1, Defs.’ Mot. to Exc. Wells, Exhibit A, Wells Rep. at 12-16; ECF No. 48-7, Defs’ Mot. to Exc. Wells, Ex. G, “Radon Samples Taken in Airport Area”; ECF No. 48-8, Defs’. Mot. to Exc. Wells, Ex. H “Table 1. Materials Stored at St. Louis Airport Storage Site”; Wells Dep. at 171:23-172:1.)

29. Dr. Wells’s opinion that releases of thorium-230 at SLAPS were in excess of the federal limits set forth in 10 C.F.R. § 20.106 (1960) was not based on annual averages. (*Mem. and Ord.* at 6-15 and 26-31; *see also* Defs.’ Mot. to Exc. Wells, Exhibit A, Wells Rep. at 12-16; ECF No. 48-10, Defs.’ Mot. to Exc. Wells, Ex. J, “Mallinckrodt Environmental Monitoring Report, 1960”; Wells Dep. at 189:7-20; 197:22.)

30. Dr. Wells’s opinion that releases of other unspecified radionuclides in soil and sediment in and around Coldwater Creek exceeded the federal limits set forth in 10 C.F.R. § 20.106 (1960) failed to identify the specific radionuclides for which releases were alleged, did not identify the annual average amount released, and did not state the applicable limit. (*Mem. and Ord.* at 29-

30; ECF No. 48-5, Defs.' Mot. to Exc. Wells, Exhibit E, Wells Supp. Report at 7-9; Wells Dep. at 224:11-225:16.)

31. The Court excluded Dr. Wells's opinion that the concentrations of radon-220 and thorium-230 at the boundary of SLAPS, and other unspecified radionuclides in soil and settlement in and around Coldwater Creek, exceeded the federal limits set forth in 10 C.F.R. § 20.106 (1960). (*Mem. and Ord.* at 30.)

32. Dr. Wells also opined that the concentrations of radon-220 and thorium-230 at the boundary of Latty Avenue exceeded the federal limits set forth in 10 C.F.R. § 20.106(b) (1960). (*Mem. and Ord.* at 30.)

33. The Court excluded Dr. Wells's opinion that that the concentrations of radon-220 and thorium-230 at the boundary of Latty Avenue exceeded the federal limits set forth in 10 C.F.R. § 20.106(b) (1960). (*Mem. and Ord.* at 30.)

34. Dr. Wells's reliance on radon measurements for SLAPS as a proxy for Latty Avenue was fundamentally unsupported because it is undisputed that the radon measurements with respect to SLAPS related to radon emissions from K-65 drums and that K-65 was never present at Latty Avenue. (*Mem. and Ord.* at 30.)

35. Dr. Wells's opinion that the concentrations of thorium-230 at the boundary of Latty Avenue breached the federal standard between 1968 and 1971 also relied on calculations using quarterly averages, when annual averaging is required to show a breach of § 20.106. (*Mem. and Ord.* at 30.)

### **III. FACTUAL BACKGROUND.**

36. Defendant Mallinckrodt LLC is a Delaware limited liability company that is the successor-in-interest to Mallinckrodt Chemical Works. (ECF No. 9, ¶ 25, Mallinckrodt's Answer.)

37. The federal government contracted with Mallinckrodt for the production of radioactive material for the Manhattan Project. (*Mem. and Ord.* at 2; Letter from R.J. Hart to Harold Yeager regarding Radiological Resurvey of Mallinckrodt Facilities Utilized in MED/AEC Contract Work dated July 6, 1977, attached as Exhibit A; Memorandum of Understanding between Mallinckrodt Chemical Works and the University of Chicago dated April 23, 1942, attached as Exhibit B; and Contract for Supplies between the United States of America and Mallinckrodt Chemical Works dated Jul 20, 1942, attached as Exhibit C.)

38. In 1946, the federal government's MED acquired an area north of the St. Louis Airport known as "SLAPS" for purposes of storing waste from the Project. (*Mem. and Ord.* at 2; ECF No. 48-2, Defs.' Mot. to Exc. Wells, Exhibit B, SLAPS Historical Synopsis from Committee Report on Disposition of St. Louis Airport Site at 1; Amendment No. 93 to Contract No. W-14-108-Eng-8 dated July 20, 1953, attached as Exhibit D.)

39. The MED, and its successor, the AEC, operated and stored radioactive waste product at SLAPS from 1946 until July 1953. (*Mem. and Ord.* at 2; ECF No. 48-2 Defs.' Mot. to Exc. Wells, Exhibit B, "SLAPS Historical Synopsis from Committee Report on Disposition of St. Louis Airport Site," at 1.)

40. The radioactive waste product stored at SLAPS included K-65, a radium-bearing residue that produced radon. (ECF No. 104, *Mem. and Ord.* at 8; ECF No. 48-7, Defs' Mot. to Exc. Wells, Ex. G, U.S. Government Mem. "Radon Samples Taken in Airport Area,"; ECF No. 48-2 Defs.' Mot. to Exc. Wells, Exhibit B, SLAPS Historical Synopsis from Committee Report on Disposition of St. Louis Airport Site at 1.)

41. The AEC removed the K-65 from SLAPS by the end of 1949. (*Mem. and Ord.* at 2; ECF No. 48-8; Defs'. Mot. to Exc. Wells, Ex. H, "Table 1. Materials Stored at St. Louis Airport Storage Site,"; ECF No. 48-4, Defs'. Mot. to Exc. Wells, Ex. D, Wells Dep. 182:9-18.)

42. The AEC contracted with Mallinckrodt to maintain SLAPS beginning in July of 1953 and continuing until February 14, 1966. (*Mem. and Ord.* at 2; ECF No. 48-1, Defs.' Mot. to Exc. Wells, Exhibit A, Wells Report at 12; Wells Dep. 107:10-12.)

43. Mallinckrodt performed all of its pertinent activities at SLAPS pursuant to contracts with the federal government and the MED and AEC provided oversight and supervision of Mallinckrodt's activities. (ECF No. 48-6, Defs.' Mot. to Exc. Wells, Exhibit F, Fleishman-Hillard Report at 133, 155-56.)

44. Some of the radioactive waste product at SLAPS was transported to an interim storage site in Hazelwood, Missouri, known as "Latty Avenue" or "HISS." (*Mem. and Ord.* at 2.)

45. Between 1969 and 1973, Cotter possessed and managed the radioactive material at HISS and Latty Avenue. (*Mem. and Ord.* at 2.)

#### **IV. AEC OVERSIGHT OF MALLINCKRODT'S WORK AND APPLICABLE REGULATIONS.**

46. The AEC required its contractors to comply with the standards it adopted. (AEC Manual Chapter 0524, *Permissible Levels of Radiation Exposure* attached hereto as Exhibit E; John Frazier, Ph.D. Report attached hereto as Exhibit F at 14; Deposition of John Frazier, Ph.D., attached hereto as Exhibit G<sup>1</sup>; Amd. No. 45 of Contract No. W-14-108 eng-8 (effective as of October 1, 1949) attached hereto as Exhibit H.)

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<sup>1</sup> Exhibit G is the portion of Dr. Frazier's deposition in which he testifies the Frazier Report contains his opinions and the basis therefore, and he would testify accordingly at trial. The Frazier Report was Exhibit 2 to Dr. Frazier's deposition.



47. The AEC adopted its radiation standards from consensus standards developed by the National Bureau of Standards (“NBS”) and National Committee on Radiation Protection and Measurement (“NCRP”). (*Maximum Permissible Radiation Exposures to Man* attached hereto as Exhibit I; Frazier Report at 14.)

48. In 1949, the NBS published Handbook 42, *Safe Handling of Radioactive Isotopes*. (NBS Handbook, attached hereto as Exhibit J; Frazier Report at 13).

49. Handbook 42 imposed the limits on radiation and radioactive materials that may be present in unrestricted areas from a Government facility. (NBS Handbook 42, attached as Exhibit J; Frazier Report at 14.)

50. In anticipation of the publication of Handbook 42, the AEC issued Bulletin GM-133 on June 10, 1949, which specified codes and standards applicable to AEC personnel and AEC contractors. (*McClurg*, ECF No. 586-3, GM-133 at 3.)

51. Regarding radiation safety, the Bulletin mandated compliance with Handbook 42 and another NBS publication, *Permissible External Dose*. (*McClurg*, ECF No. 586-3, GM-133 at 3.)

52. The Atomic Energy Act of 1954 specifically authorized the AEC “to govern any activity authorized pursuant to this chapter, including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activity, in order to protect health and to minimize danger to life or property.” 42 U.S.C. §§ 2201(i)(3) (1954).

53. Starting in 1957, the AEC issued Manual Chapters, rather than the Bulletins. (AEC Manual Chapter 0524, *Permissible Levels of Radiation Exposure* attached as Exhibit E; Frazier Report at 14.)

54. The Manual Chapters expressly adopted specific NBS Handbooks and successive versions of the Manual Chapters were in effect until May 5, 1980. (U.S. Department of Energy *Environmental Protection, Safety, and Health Protection Program for DOE Operations*, attached hereto as Exhibit K; Frazier Report at 18-19.)

55. The standards for AEC licensees (i.e., 10 C.F.R. § 20) substantially agree with NBS Handbooks 52 and 59 which contain the standards applicable to AEC contractors during the relevant time periods. (10 C.F.R. Part 20, 22 FR 548, *Standards for Protection Against Radiation*, Atomic Energy Commission, Washington, DC, January 8, 1958 attached hereto as Exhibit L; Handbook 52, *Maximum Permissible Amounts of Radioisotopes in the Human Body and Maximum Permissible Concentrations in Air and Water*, National Bureau of Standards, Washington, DC, March 20, 1953 attached hereto as Exhibit M; Handbook 59, *Permissible Dose from External Sources of Ionizing Radiation*, National Bureau of Standards, Washington, DC, September 24, 1954 attached hereto as Exhibit N; *A Review of the History of U.S. Radiation Protection Regulations, Recommendation, and Standards*, attached hereto as Exhibit O; Frazier Report at 21.)

56. Mallinckrodt was contractually bound to follow the MED and AEC regulations which obligated Mallinckrodt to perform all of its work in accordance with “all health and safety regulations and requirements of the [AEC].” (Amd. No. 45 of Contract No. W-14-108 eng-8 (effective as of October 1, 1949) attached hereto as Exhibit H.)

Dated: May 6, 2022

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 6th day of May, 2022, I served the above to the following counsel of record via the Court's electronic filing system.

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